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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,639	02/22/2005	Robert Short	5585-70349-01	9198

24197 7590 08/08/2007

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
08/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,639	SHORT ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *27-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1 – 26 and species of keratinocytes in the reply filed on May 21, 2007 is acknowledged. The traversal is on the ground(s) that the groups have the same special technical feature. This is not found persuasive because as indicated by the rejections below, the groups do not contain a special technical feature which contributes over the prior art. Regarding the species election, applicant's argument are persuasive insofar as all keratinocytes should be readable on the elected species. Moreover, all types of keratinocytes have been included and examined as the elected species.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1 – 52 are pending; claims 27 – 52 are withdrawn; claims 1 – 26 have been considered on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 4, 10 – 17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Naughton et al. (US 6372494)

Applicant claims a method for culturing mammalian cells, the method comprising providing a culture vessel comprising mammalian cells, a cell culture support comprising a substrate with a acid monomer polymer attached to the surface, fibroblast feeder cells, and a serum free culture medium; and providing a cell culture medium and conditions that promote proliferation of the cells. The cells are human; are undifferentiated; and are keratinocytes selected from epidermal, intestinal or oral mucosa. The substrate comprises a non-porous polymer; solid phase substrate; is porous; woven; non-woven. The surface polymer comprises an acid content of at least 2%, 2 – 20%, or more than 20%; or the polymer is an acid copolymer.

Naughton teaches methods for culturing mammalian cells (abstract), the methods comprising providing a culture vessel (col.9 line 66 – col.10 line 5), mammalian cells (abstract), a 3D support (a cell culture support) (col.6) that is coated with polylysine (col.11 line 54- col.12 line 14) (an acid monomer attached to the surface), feeder fibroblasts (col.9 line 35-48, col.10 line 16-26,66-67), and DMEM, Ham's F12, RPMI or McCoys media (serum free media) (col.7 line 40-50); wherein conditions are such that cells are proliferated (abstract, claims). The mammalian cells may include epithelial skin cells (epidermal) such as keratinocytes from the oral or intestinal mucosa (col.14 line 49 – col.14 line 14). The substrate may be formed from porous, non-porous, solid, woven, or non-woven materials, and may take on any shape (col.11 line 55 – col.12 line 14, col.6 line 43-49). The substrate's surface may be treated with acetic acid and polylysine (or has the claimed acid content) (col.12 line 5-14).

Although the reference does not specifically identify human cells, the teachings are clearly drawn to human conditions and cells (col.19 line 39-60).

Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 – 17 and 21 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton.

Applicant claims a method for culturing mammalian cells, the method comprising providing a culture vessel comprising mammalian cells, a cell culture support comprising a

substrate with a acid monomer polymer attached to the surface, fibroblast feeder cells, and a serum free culture medium; and providing a cell culture medium and conditions that promote proliferation of the cells. The cells are human; are undifferentiated; and are keratinocytes selected from epidermal, intestinal or oral mucosa. The substrate comprises a non-porous polymer; solid phase substrate; is porous; woven; non-woven. The surface polymer comprises an acid content of at least 2%, 2 – 20%, or more than 20%; or the polymer is an acid copolymer. The ratio of mammalian cells to fibroblasts is between 1:1 – 1:5 or is about 5:1; the cells are seeded at about 0.75x10^4 cells/mm2. The keratinocytes and fibroblasts are human and autologous. The fibroblasts are non-proliferative; rendered such by lowering calcium in the growth medium; are human; are oral or dermal.

Naughton teaches methods for culturing mammalian cells (abstract), the methods comprising providing a culture vessel (col.9 line 66 – col.10 line 5), mammalian cells (abstract), a 3D support (a cell culture support) (col.6) that is coated with polylysine (col.11 line 54- col.12 line 14) (an acid monomer attached to the surface), feeder fibroblasts (col.9 line 35-48, col.10 line 16-26,66-67), and DMEM, Ham's F12, RPMI or McCoys media (serum free media) (col.7 line 40-50); wherein conditions are such that cells are proliferated (abstract, claims). The mammalian cells may include epithelial skin cells (epidermal) such as keratinocytes from the oral or intestinal mucosa (col.14 line 49 – col.14 line 14). The substrate may be formed from porous, non-porous, solid, woven, or non-woven materials, and may take on any shape (col.11 line 55 – col.12 line 14, col.6 line 43-49). The substrate's surface may be treated with acetic acid and polylysine (or has the claimed acid content) (col.12 line 5-14). Although the reference does

not specifically identify human cells, the teachings are clearly drawn to human conditions and cells (col.19 line 39-60).

The reference does not teach the cell ratio or seeded spacing as claimed, or wherein the cells are autologous. However, at the time of the claimed invention, these limitations where well know to be optimized as a matter of routine practice. In addition, autologous cells were commonly used in such applications. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to seed autologous cells in the claimed ratios and spacing as a matter of routine practice and experimentation.

The reference does not teach the method wherein the fibroblasts are non-proliferative; rendered such by lowering calcium in the growth medium; or are oral or dermal derived. However, the reference does teach that the extent of growth of the stromal cells (feeder fibroblasts) will vary depending on type of tissue to be grown (col.10 line 61-65) and that the cells are derived from the same source as the cells to be cultured (col.10 line 30-35). Thus, in following the teachings of Naughton, one would know to optimize the growth period of the feeder cells as a matter of routine experimentation. Furthermore, it is noted that the references identifies the claimed sources of cells to include oral or dermal sources (col.14 line 49 – col.14 line 14). Therefore, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Naughton and routine practice to optimize the growth of feeder cells in addition to selecting the source of cells, as a matter of routine practice and experimentation.

7. Claims 1 – 4 and 10 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton in view of Kiba et al. (JP 402163077).

Applicant claims a method for culturing mammalian cells, the method comprising providing a culture vessel comprising mammalian cells, a cell culture support comprising a substrate with a acid monomer polymer attached to the surface, fibroblast feeder cells, and a serum free culture medium; and providing a cell culture medium and conditions that promote proliferation of the cells. The cells are human; are undifferentiated; and are keratinocytes selected from epidermal, intestinal or oral mucosa. The substrate comprises a non-porous polymer; solid phase substrate; is porous; woven; non-woven. The surface polymer comprises an acid content of at least 2%, 2 – 20%, or more than 20%; or the polymer is an acid copolymer. The polymer is an acrylic acid monomer with at least 2% acid, 2 – 10% or 4 – 5% acid.

Naughton teaches methods for culturing mammalian cells (abstract), the methods comprising providing a culture vessel (col.9 line 66 – col.10 line 5), mammalian cells (abstract), a 3D support (a cell culture support) (col.6) that is coated with polylysine (col.11 line 54- col.12 line 14) (an acid monomer attached to the surface), feeder fibroblasts (col.9 line 35-48, col.10 line 16-26,66-67), and DMEM, Ham's F12, RPMI or McCoys media (serum free media) (col.7 line 40-50); wherein conditions are such that cells are proliferated (abstract, claims). The mammalian cells may include epithelial skin cells (epidermal) such as keratinocytes from the oral or intestinal mucosa (col.14 line 49 – col.14 line 14). The substrate may be formed from porous, non-porous, solid, woven, or non-woven materials, and may take on any shape (col.11 line 55 – col.12 line 14, col.6 line 43-49). The substrate's surface may be treated with acetic acid and polylysine (or has the claimed acid content) (col.12 line 5-14). Although the reference does not specifically identify human cells, the teachings are clearly drawn to human conditions and cells (col.19 line 39-60).

Naughton does not teach coating the substrate with an acrylic acid monomer with the claimed acid content. However, Kiba teaches methods for culturing cells wherein the substrate is coated with acrylic acid (abstract) wherein the substrate provides a consistent environment for the cells (abstract). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the substrate coating of Kiba in the methods of Naughton because it was known to provide stable environments for cell cultures. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Kiba to coat the substrate of Naughton with the claimed polymer with a reasonable expectation for successfully culturing mammalian cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

August 2, 2007